***Enquiries*:** variations@sahpra.org.za

CLINICAL APPROVAL LETTER: POST REGISTRATION APPLICATIONS

Clinical approval date	06 May 2026
Applicant's cover letter date	16 January 2026
Applicant	Adcock Ingram Limited
Proprietary name(s) (including duplicates)	Allergex Elixir
API(s)	Chlorphenamine Maleate
Registration number(s)	C807 (Act 101 of 1965)
Sequence no	0014

Dear Sir/Madam,

Kindly be informed that the Authority has completed the evaluation of the above-mentioned Professional Information (PI) and Patient Information Leaflet (PIL) variation application.

1. The amendments to the PI and PIL are approved.
2. The PI and PIL be accepted as the currently approved PI and PIL
3. The date of revision reflected on this PI and PIL should be**: 06 May 2026**
4. The final dated version of the above PI and PIL must be submitted via docubridge in a closing sequence using the Sequence Type "Closing sequence" and Sequence Description "Approved " updated PI and PIL within 10 working days.
5. The approved PI and PIL must be uploaded into the SAHPRA repository within 10 working days.

Note to applicant: Amendments to any quality aspects of the medicine within the PI and PIL are subject to P&A unit approval and may only be implemented in the PI if approved by the P&A unit.

Yours Faithfully,

L.DHLAMINI

MANAGER: CLINICAL POST-REGISTRATION UNIT

SCHEDULING STATUS: **S2**

1. NAME OF MEDICINE

ALLERGEX® ELIXIR (2 mg/ 5 ml)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Chlorpheniramine maleate	2 mg

Preservatives:

Methylparaben	0,12 % *m/v*
Propylparaben	0,016 % *m/v*

Contains sugar:

Sucrose	2,55 g
Contains Ethanol	0,50 % v/v

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Clear raspberry red syrup with fruity-clove odour. Free with visible matter.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Allergic and anaphylactic conditions such as hay fever, vasomotor rhinitis, urticaria, angioedema, drug reactions, contact dermatitis, atopic dermatitis, insect bites, pruritus and pruritus vulvae.

4.2 Posology and method of administration

Adults: 10 ml every 4 to 6 hours, up to a maximum of 60 mL in 24 hours.

Children: 2-5 years: ½ - 1 medicine measure 3 times daily.

6-12 years: 2 medicine measure 3 or 4 times daily.

Not recommended for children under 2 year of age.

Method of administration

Oral administration

4.3 Contraindications

Hypersensitivity to Chlorpheniramine or to any of the excipients of ALLERGEX

Elixir listed in section 6.1.

Epilepsy. Premature infants or neonates. Acute attacks of asthma.

Do not use in children under 2 year of age.

4.4 Special warnings and precautions for use

- Avoid the use of alcohol or CNS depressants
- Inform your physician if taking other medications (see section 4.5).
- Drowsiness may occur (see section 4.4).
- Geriatrics – Dizziness, confusion and hypotension is more likely to occur in geriatric patients taking antihistamines.

Due to the antimuscarinic properties, chlorpheniramine maleate should be used with care in conditions such as narrow angle glaucoma, urinary retention and prostatic hypertrophy.

Antihistamines may suppress positive skin test results and should be stopped several days before the test.

ALLERGEX ELIXIR contains sucrose

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

ALLERGEX ELIXIR contains methylparaben and propylparaben

May cause allergic reactions (possible delayed).

ALLERGEX ELIXIR contains ethanol

This medicine contains 19.7 mg of alcohol (ethanol) in each 5 ml, which is equivalent to

0,02496 ml/ 5ml (0,50 % v/v). The small amount of alcohol in this medicine will not have any noticeable side effects.

4.5 Interaction with other medicines and other forms of interactions

Monoamine oxidase inhibitors may enhance the antimuscarinic effects of antihistamines and antihistamines have an additive antimuscarinic action with other antimuscarinic medicines such as atropine and tricyclic antidepressants.

Sedating antihistamines may enhance the sedative effects of the CNS depressants including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives, and antipsychotics.

Antihistamines may suppress positive skin test results and should be stopped several days before the test.

4.6 Fertility, pregnancy and lactation

Fertility

No data available

Pregnancy

ALLERGEX ELIXIR should not be administered during the early months of pregnancy because of foetal abnormalities in animal studies.

Lactation

ALLERGEX ELIXIR is not recommended in nursing infants as it may cause unusual excitement or irritability.

4.7 Effects on ability to drive and use machines

The use of this medicine leads to drowsiness which is aggravated by the simultaneous intake of alcohol. Patients should be warned not to drive a motor vehicle, operate dangerous machinery or climb dangerous heights, as impaired decision making could lead to accidents.

4.8 Undesirable effects

System organ class	**Frequency**	**Undesirable effects**
Blood and lymphatic system disorders	Unknown	Haemolytic anaemia, blood dyscrasias
Immune system disorders	Unknown	Allergic reaction and cross sensitivity to related medicines may be produced
Metabolism and nutritional disorder	Unknown	Increased appetite
Nervous system disorders	Frequent	Sedation
	Unknown	Lassitude, incoordination, dizziness, headache
Eye disorders	Frequent	Blurred vision

Ear and labyrinth disorder	Unknown	Tinnitus
Cardiac disorders	Frequent	Tachycardia
	Unknown	Tremors, convulsions
Vascular disorders	Unknown	Hypotension
Respiratory, thoracic and mediastinal disorders	Unknown	Tightness of the chest
Gastrointestinal disorders	Frequent	Nausea
	Unknown	Vomiting, diarrhoea or constipation, anorexia and epigastric pain
Renal and urinary disorders	Unknown	Difficulty in micturition and dysuria
Musculoskeletal and connective tissue disorders	Unknown	Muscular weakness

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

May also report to Adcock Ingram Limited using the following email:

Adcock.AEReports@adcock.com

4.9 Overdose

Overdosage may be fatal especially in infants and children in whom the main symptoms are Central Nervous System (CNS) stimulation and antimuscarinic effects, including ataxia, excitement, hallucinations, muscle tremors, convulsions, dilated pupils, dry mouth, flushed face and hyperpyrexia. Deepening coma, cardiorespiratory collapse and death may occur.

In adults, the usual symptoms are of CNS depression with drowsiness, coma and convulsions. Hypotension may occur. Elderly patients are more susceptible to the CNS depressant and hypotensive effects even at therapeutic levels.

Treatment: Symptomatic and supportive.

5. PHARMACEUTICAL PROPERTIES

5.1 Pharmacodynamics properties

Category and Class: A 5.7.1 Medicines affecting autonomic functions

Pharmacotherapeutic Group: Antihistamines

ATC code: R06AB02

Mechanism of action

Chlorpheniramine maleate is an antihistamine that acts by competing with histamine for H1-receptor sites on effector cells. It thereby prevents but does not reverse responses mediated by histamine alone.

5.2 Pharmacokinetic properties

ALLERGEX ELIXIR is well absorbed from the gastrointestinal tract. Following oral administration, peak plasm concentrations are achieved in 2-3 hours and effects usually last 4-6 hours. It has a plasm half-life of about 4-8 hours. Widely distributed throughout the body, including the central nervous system, and is excreted as metabolites in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol (E 422)

Ethanol 96 %

Oil of aniseed 339601

Oil of coriander 420913

Oil of cloves 400606

Oil of cassia 100091

Oil of orange Valenica LR 12772

Colour red F1127 C.I 14720/42090

Sucrose/Sucrose solution

Methylparaben (E 218)

Propylparaben (E 216)

Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 ºC, in a cool place. Protect from light.

KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

50 ml Amber glass bottle and 50 ml amber PVC bottle with 24 mm snap on pilfer proof.

100 ml Amber glass, 100 ml Amber PET bottle with 28 mm EXPE screw generic closure and 100 ml Amber PVC bottle with 24 mm white snap-on cap.

2,5 L amber HDPE container with white polypropylene screw.

200 ml PVC bottle medical round with 31 mm L.L.D.P.E closures snap on pilfer and 200 ml amber glass 28 mm MEDROPP GENERIC bottle with white polypropylene 28 mm cap with liner.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand,1685

Customer Care: 0860 ADCOCK / 232625

8. REGISTRATION NUMBER

C807 (Act 101/1965)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

September 1970

10. DATE OF REVISION OF TEXT

To be allocated

Namibia: NS1 14/57.1/0479

Botswana: B9324115 S3

SCHEDULING STATUS S2

ALLERGEX® ELIXIR (2mg/ 5 ml)

Chlorphenamine maleate 2 mg

Preservatives:

Methylparaben *0,12 % m/v*

Propylparaben *0,016 % m/v*

Contains sugar:

Sucrose 2,55 g

Contains Ethanol 0,50 % *v/v*

Read all of this leaflet carefully because it contains important information for you.

ALLERGEX ELIXIR is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **ALLERGEX ELIXIR** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **ALLERGEX ELIXIR** with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. WHAT ALLERGEX TABLETS IS AND WHAT IT IS USED FOR

ALLERGEX ELIXIR is an antihistamine that is used to relieve or prevent allergic symptoms. redness, swelling, tenderness and irritation. ALLERGEX ELIXIR is used for the treatment of allergic and anaphylactic conditions such as hay fever, vasomotor rhinitis (allergy in

the nose when the small blood vessels in the nose dilate causing nasal congestion), urticaria (itchy rash that appears on the skin), angioedema (swelling under the skin), drug reactions, contact dermatitis, atopic dermatitis, insect bites, pruritus and pruritus vulvae.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ALLERGEX ELIXIR

Do not take ALLERGEX ELIXIR

- If you are hypersensitive (allergic) to chlorphenamine maleate or any of the other ingredients of ALLERGEX ELIXIR (listed in section 6).
- If your child is a premature infant or neonate
- If your child is under 2 years of age
- If you are experiencing acute attacks of asthma

Warnings and precautions

Take special care with **ALLERGEX ELIXIR**

- If you have narrow angle glaucoma, urinary retention and prostatic hypertrophy.
- This medicine may cause some people to become drowsy or less alert than they are normally.
- Make sure you know how to react to **ALLERGEX ELIXIR** before you drive, use machines, or do anything else that could be dangerous if you are not alert.
- **ALLERGEX ELIXIR** may add to the effects of alcohol and other CNS depressants (medicines that slow down the nervous system, possibly causing drowsiness). Some examples of CNS depressants are sedatives, tranquilizers, or sleeping medicine; prescription pain medicine or narcotics; barbiturates, medicine for seizure, muscle relaxants or anaesthetics.

Other medicines and ALLERGEX ELIXIR

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

- Monoamine oxidase inhibitors, antimuscarinic medicines such as atropine and antidepressants - *Side-effects, such as dryness of the mouth, with antihistamines may be more likely to occur.
- Central nervous system (CNS) depressants (medicines that cause drowsiness) – Effects, such as drowsiness, of CNS depressants including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and antipsychotics may be worsened.

- Before you have any skin tests for allergies, tell your doctor in charge that you are taking this medicine. The results of the test may be affected by this medicine.

Pregnancy, breastfeeding and fertility

The safety of **ALLERGEX ELIXIR** has not been studied in pregnant women.

- Use is not recommended in nursing mothers as babies are susceptible to the side-effects of **ALLERGEX ELIXIR**, such as unusual excitement or irritability.
- If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking this medicine.

Driving and using machinery

It is not always possible to predict to what extent **ALLERGEX ELIXIR** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **ALLERGEX ELIXIR** affects them.

ALLERGEX ELIXIR contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

ALLERGEX ELIXIR contains methylparaben and propylparaben

May cause allergic reactions (possible delayed).

ALLERGEX ELIXIR contains ethanol

This medicine contains 19.7 mg of alcohol (ethanol) in each 5 ml, which is equivalent to 0,02496 ml/5ml (0,50 % v/v). The small amount of alcohol in this medicine will not have any noticeable side effects.

3. HOW TO TAKE ALLERGEX ELIXIR

Do not share medicines prescribed for you by any other person. Always take ALLERGEX ELIXIR exactly as described in this leaflet or as your doctor, pharmacist, or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose is:

Adults: 10 mL every 4 to 6 hours, up to a maximum of 60 mL in 24 hours.

Children (2-5 years): ½-1 medicine measure 3 times daily

6-12 years: 2 medicine measures 3 to 4 times daily

If you take more ALLERGEX ELIXIR than you should

Overdosage may lead to death, especially in infants and children in whom the following symptoms occur: ataxia (incoordination), excitement, hallucinations, muscle tremors, convulsions (seizures), dryness of mouth, dilated pupils (widened pupils), flushed or red face and extremely high fever. In adults the usual symptoms are drowsiness, coma and convulsions (seizures). Low blood pressure may occur. Elderly patients are usually more sensitive to the effects of **ALLERGEX ELIXIR.**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ALLERGEX ELIXIR

Do not take/ receive a double dose to make up for forgotten individual doses. If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the dose that you missed.

If you stop taking ALLERGEX ELIXIR

Take **ALLERGEX ELIXIR** for as long as your doctor recommends. Don’t stop unless your doctor advises you to.

4. Possible side-effects

ALLERGEX ELIXIR can have side effects. Not all side effects reported for **ALLERGEX ELIXIR** are included in this leaflet. Should your general health worsen or if you experience untoward effects while taking **ALLERGEX ELIXIR**, please consult your health care provider for advice.

If any of the following happens, stop taking/ using ALLERGEX ELIXIR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions
- Raised and itchy rash (hives)
- Swelling, sometimes of the face or mouth can cause difficulty breathing
- Fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to ALLERGEX ELIXIR. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects

- sedation (calming or relaxing state)
- blurred vision
- tachycardia (rapid heart rate that could be regular or irregular)
- nausea (feeling that one is about to vomit)

Side effects with an unknown frequency

- serious blood disorders
- allergic reactions
- cross-sensitivity to medicines (allergic reactions to similar medicines)
- increased appetite
- incoordination (inability to use different parts of the body smoothly together)
- dizziness
- headache
- tinnitus (ringing in the ears)
- tremors (involuntary, rhythmic shaking or trembling of a body part)
- convulsions (loss of consciousness)

- hypotension (low blood pressure)
- chest tightness
- vomiting (to be sick)
- diarrhoea (frequent or loose watery stools)
- constipation
- epigastric pain (feeling of discomfort or aching in the upper abdomen)
- difficulty in emptying urine from bladder
- dysuria (discomfort, pain or burning when urinating)
- muscle weakness

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide information on the safety of ALLERGEX ELIXIR.

May also report to Adcock Ingram Limited using the following email:

Adcock.AEReports@adcock.com

5. HOW TO STORE ALLERGEX ELIXIR

Store at or below 25 °C in a cool place

Protect from light

KEEP OUT OF REACH OF CHILDREN

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ALLERGEX ELIXIR contain:

The active substance is chlorpheniramine maleate

The other ingredients are glycerol (E 422), ethanol 96 %, oil of aniseed 339601, oil of coriander 420913, oil of cloves 400606, oil of cassia 100091, oil of orange Valencia LR 12772, colour red F1127

C.I 14720/42090, sucrose/sucrose solution, methylparaben (0,12 % *m/v*), propylparaben (0,016 % *m/v),* purified water.

What ALLERGEX ELIXIR looks like and contents of the pack

Clear raspberry red syrup with fruity-clove odour. Free with visible matter.

50 ml Amber glass bottle and 50 ml amber PVC bottle with 24 mm snap on pilfer proof.

100 ml Amber glass, 100 ml Amber PET bottle with 28 mm EXPE screw generic closure

100 ml Amber PVC bottle with 24 mm white snap-on cap

200 ml PVC bottle medical round with 31 mm L.L.D.P.E closures snap on pilfer

200 ml Amber glass 28 mm MEDROPP GENERIC bottle with white polypropylene 28 mm cap with liner

Holder of Certificate of Registration

Adcock Ingram Limited

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Customer Care: 0860 ADCOCK / 232625

This leaflet was revised in

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C 807 (Act 101 of 1965)

Namibia: NS1 14/5.7.1/0479

Botswana: B9324115 S3